Title:

Quality Control Record Sheet Insulin Ab 3 QC Data

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Approved by: Janet Bradbury

Document:

wi/qcrs/0.08b

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Tracer iodination date: 25 January 2024

Kit lot number: 3INK340

Kit expiry date: 22 March 2024

| 125 _{I - Insulin} | Lot No. | IT340R | Expiry Date: | 22 MAR 2024 |
|----------------------------|---------|-----------------|--------------|-------------|
| Assay Buffer | Lot No. | MIAB149 | Expiry Date: | 05 MAY 2025 |
| Anti-human IgG | Lot No. | 187PG | Expiry Date: | 28 MAR 2025 |
| Calibrators | Lot No. | IMS38B | Expiry Date: | 26 FEB 2025 |
| Negative Control | Lot No. | IN131 | Expiry Date: | 06 JUL 2024 |
| Kit Controls | Lot No. | IMCa38B/IMCb38B | Expiry Date: | 26 FEB 2025 |

Total cpm in 25 μ l ¹²⁵l - Insulin

27932

| Sample | % 125 _{I - Insulin} bound | <u>u/mL</u> | Range u/mL |
|--------------------|---------------------------------------|-------------|---------------|
| Negative control | 1.1 | | |
| INS-Ab calibrator: | | | |
| 0.4 u/mL | 2.4 | | |
| 1 u/mL | 4.6 | | |
| 10 u/mL | 16.2 | | |
| 50 u/mL | 54.8 | | |
| | | | |
| Control I | 4.3 | 0.86 | 0.5 - 1.7 |
| Control II | 18.5 | 11.5 | 8 – 18 |

Materials of human origin used in the manufacture of this product have been tested and found non-reactive for HIV1 and 2 and HCV antibodies at the time of testing.

Assay Date:

30 Jan 2024

Performed by:

J DAVIES

Signature:

Position:

Senior Scientist

Authorised by: OR G FLOOD

Signature: 5

Position: Head of Quality Control

Date: 30TT JAN 2024